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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,289	07/14/2003	Yanbin Liang	17561 (AP)	3328

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ALLERGAN, INC.
2525 DUPONT DRIVE, T2-7H
IRVINE, CA 92612-1599

EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,289	LIANG ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) *5,6,8-10,13-19,22-32,35-45 and 48-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2 and 7* is/are rejected.

7)☒ Claim(s) *1,3,4,11,12,20,21,33,34,46 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1) Claims 1 to 58 are pending in the instant application.

2) Claims 11, 12, 20, 21, 33, 34, 46 and 47 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must depend from other claims in the alternative only. See MPEP § 608.01(n). Accordingly, these claims have not been further treated on the merits.

The restriction requirement between claims 1 and 2, in so far as they relate to SEQ ID NO:24, which corresponds to amino acids 267 to 296 of SEQ ID NO:8, and claims 3, 4 and 7 in so far as they relate to SEQ ID NO:8, is withdrawn in view of the fact that claims 1 and 2 fully encompass the subject matter of claims 3, 4 and 7.

Claims 5 and 6, in so far as they relate to a "binding agent" which binds to SEQ ID NO:24, and claims 54 to 58 in so far as they relate to an isolated nucleic acid encoding SEQ ID NO:8, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 24 July of 2006. The traversal is on the ground(s) that a search of the different inventions in a single application would pose no undue burden. This is not found persuasive because M.P.E.P. 803 states that:

> "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant."

Serious burden was shown in the original requirement by the separate classification and separate status in the art of the different inventions. An isolate polypeptide, an "agent" that binds thereto, and an isolate nucleic acid encoding a polypeptide are three

chemically unrelated compounds each of which can be made and used without the others. They do not reflect a common inventive concept because they lack a common substantial structural feature or combination of features that distinguishes them as a group from the prior art. Further, the disclosure of one of these compounds in the prior art does not necessarily anticipate or render obvious either of the other two compounds. See *In re Deuel*, 24 USPQ2d 1210 (Fed. Cir. 1995). Applicant has provided neither a showing nor evidence to the contrary. In addition, Applicant is advised that classification refers to both a class and a subclass. Two inventions that belong to a common class but different subclasses have different classifications.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8 to 10, 13 to 19, 22 to 32, 35 to 45 and 48 to 53, and claims 1 to 7 in so far as they relate to an amino acid sequence recited therein other than SEQ ID NO:8 or 24, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 July of 2006. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1 to 4 and 7are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

> "Since the decisions in In re Weber **,198 USPQ 328 (CCPA 1978); and In re Haas, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity

of invention, In re Harnish , 631 F.2d 716, 206 USPQ 300 (CCPA 1980); Ex Parte Hozumi , 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility."

The amino acid sequences presented in SEQ ID NOs: 17 to 25 appear to be structurally unrelated and, therefore, do not share a substantial structural feature. The different amino acid sequences presented in SEQ ID NOs: 2, 4, 6, 8, 10 and 12 do not reflect a common inventive concept because, as shown by Figure 7 of the instant application, they lack a common feature or combination of features that distinguishes them as a group from the prior art protein identified therein as "FP WT".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. These claims encompass subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims encompass an isolated polypeptide which is a "conservative variant" of the amino acid sequence presented in SEQ ID NO:24 of the instant application. The text beginning in line 19 on page 6 of the instant specification states that "[t]he present invention is directed to the exciting discovery of several novel FP receptor variants" which" can be used to determine and refine the specificity of binding of compounds that bind to the known wild-type FP receptor" and that "[t]hese FP

receptor variants also can be used to identify compounds that differentially modulate or bind to a first FP receptor variant in relation to a second FP receptor variant or wild-type FP receptor". The text beginning in the first paragraph on page 23 of the instant specification states that "in reference to a specified amino acid sequence such as one of SEQ ID NOS:17-25, a "conservative variant" is a sequence in which a first amino acid is replaced by another amino acid or amino acid analog having at least one biochemical property similar to that of the first amino acid; similar properties include, yet are not limited to, similar size, charge, hydrophobicity or hydrogen-bonding capacity". Page 24 of the specification asserts that "[I]t is understood that a conservative variant of one of SEQ ID NOS: 17-25 can have one, two, three, four, five, six or more amino acid substitutions relative to the specified sequence and that such a conservative variant can include naturally and non-naturally occurring amino acid analogs". The instant claims, therefore, encompass a non-naturally occurring protein whose amino acid sequence deviates from SEQ ID NO:24 by every amino acid in that sequence.

However, the instant specification does not provide the guidance needed use a polypeptide comprising anything less than the entire, naturally occurring amino acid sequence presented in SEQ ID NO:24. The only manner described in the instant specification of using the claimed polypeptide is in the identification of compounds that have potential medicinal use because of their ability to agonize or antagonize a mammalian FP receptor protein comprising that sequence. The claimed invention is only useful in so far as the protein employed an assay of the instant invention responds

in a manner that is predictive of an authentic physiological response. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

One of ordinary skill in the art of receptor biology would not reasonably believe that the majority of physical peptide embodiments having at least one conservative amino acid substitution in the amino acid sequence of SEQ ID NO:24 are going to be functional as part of a complete FP receptor protein, much less be capable of producing an authentic response. Because the instant specification does not identify those amino acid residues in SEQ ID NO:24, or SEQ ID NO:8 for that matter, which are critical to the structural and functional integrity of an FP receptor protein comprising that sequence, identify a structurally analogous protein for which this information is known and could be applied to the instant protein by extrapolation, or even provide a single working example of an intentionally modified FP receptor protein of the instant invention, an artisan can not change even a single residue within the amino acid sequence of SEQ ID NO:24 and

predict the effects of that change on the performance of an FP receptor protein comprising that sequence "by resort to known scientific law". Unless one can predict, with reasonable confidence, that an intentionally modified FP receptor protein is going to produce a response that is predictive of a native mammalian FP receptor protein, the information obtained from a process that uses that modified protein is of no practical value.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is vague and indefinite because there is no antecedent basis for "the exogenously expressed polypeptide".

An isolated polypeptide comprising the amino acid sequence presented in SEQ ID NO:8 or 24 of the instant application was not taught or suggested by the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800